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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,213	GOOD ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 January 2004 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration filed 8 October 2005 is defective. A new oath or declaration in compliance with 37 CFR § 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR § 1.52(c).

Drawings

2. New corrected drawings in compliance with 37 CFR § 1.121(d) are required in this application because Figures 3 and 5 do not comply with the Sequence Rules (see below), Figures 21A, 21B, 22 and 23 fail to comply with 37 CFR 1.84(g), said figures contain frames around the views. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. See pages 69-72 of the specification. Rule 37 CFR § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the

references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See Figures 3 and 5. However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825. Applicant may obviate this issue by inserting by amendment the SEQ ID NO: into the Brief Description of the Drawing, page 6 of the specification.

Failure to comply with these requirements will be held as non-responsive to this Office action.

5. The disclosure is objected to because of the following informalities:

The first line of the specification should be amended to reflect that parent Application 10/321,718 is now abandoned.

The text at page 17, ¶ 0038, last two lines, appears to be irrelevant to the disclosure, it appears to be an editorial note.

Figures in the specification on pages 64 and 65 are objected to as failing to comply with 37 CFR § 1.58(a).

Appropriate correction is required.

Claim Objections

6. Claims 7, 14, 19, 26, 28 and 31 are objected to because of the following informalities:

Claims 7 and 19 are objected to for reciting a list of species using improper Markush language, "comprising" should be amended to read -- consisting of --.

At claim 28, line 1, "a plant" should read -- the plant -- in referring to the invention of claim 1.

Claims 14, 26 and 31 are objected to because they have two periods at the end of the sentence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 10, 11, 15, 18, 22, 27 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 18 and 22 are indefinite because it is unclear if the implied transgene is what confers the elevated levels of one or more nitrogen utilizing proteins, or if such a characteristic, elevated levels of one or more nitrogen utilizing proteins, is an inherent property of the non-naturally occurring plant or plant part, hence the metes and bounds of the claim are unclear.

Claim 11 is indefinite because the phrase "salt tolerant plant or plant part" lacks proper antecedent basis in claim 1 or 10.

At claims 15, 27 and 32 are indefinite because the use of the non-art recognized limitation "the btg-26 promoter" which does not teach the metes and bounds of the

claimed invention. Amending the claim to recite -- the btg-26 promoter of SEQ ID NO: 1 -- would obviate this rejection.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-13, 15-25, 27-30 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a non-naturally occurring plant comprising elevated levels of one or more nitrogen utilization proteins specifically localized to the root epidermis, and a method of making same by transforming a plant with a nucleic acid encoding a nitrogen utilization protein operably linked to a root-epidermis-specific promoter.

Applicant describes a root-epidermis-specific promoter designated by Applicant as "the btg-26 promoter" and described in SEQ ID NO: 1. Applicant describes operably linking a coding region encoding an alanine aminotransferase (AlaAT) to said promoter at pages 45-46 of the specification.

Applicant does not describe the genus of non-naturally occurring plants comprising elevated levels of one or more nitrogen utilization proteins specifically localized to the root epidermis, nor does Applicant describe the genus of root-epidermis-specific promoters encompassed by the claims.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed. See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

11. Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a transgenic plant with enhanced nitrogen assimilation/metabolism transformed with a construct comprising SEQ ID NO: 1, the btg-26 promoter from *Brassica napus*, operably linked to a nucleic acid sequence encoding the barley alanine aminotransferase as depicted in Figure 5 (SEQ ID NO: 2) and a method of making said transgenic plant, does not reasonably provide enablement for a transgenic plant with enhanced nitrogen assimilation/metabolism transformed with a construct comprising any promoter or stress activated promoter operably linked to a nucleic acid sequence encoding any alanine aminotransferase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a non-naturally occurring plant comprising elevated levels of one or more nitrogen utilization proteins specifically localized to the root epidermis, and

a method of making same by transforming a plant with a nucleic acid encoding a nitrogen utilization protein operably linked to a root-epidermis-specific promoter.

Applicant teaches a root-epidermis-specific promoter designated by Applicant as "the btg-26 promoter" and described in SEQ ID NO: 1. Applicant teaches operably linking a coding region encoding an alanine aminotransferase (AlaAT) to said promoter at pages 45-46 of the specification.

Applicant does not teach the genus of non-naturally occurring plants comprising elevated levels of one or more nitrogen utilization proteins specifically localized to the root epidermis, nor does Applicant teach the genus of root-epidermis-specific promoters encompassed by the claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make the transgenic plant of the instant invention as broadly claimed. Applicant has taught that the CaMV promoter operably linked to a nucleic acid encoding a barley alanine aminotransferase (AlaAT) polypeptide does not differ from a control plant at pages 49-50 of the specification. The CaMV promoter is know in the art to be constitutively expressed, and to have activity in

plant roots. The art teaches that at the time of Applicant's invention only a limited number of nucleic acid sequences encoding alanine aminotransferase were know in the art. Son *et al* (1992, Plant Molecular Biology 20:705-713) teach that *Panicum miliaceum* comprises at least three genes encoding an alanine aminotransferase, but use of the AlaAT-2 cDNA to identify other nucleic acid sequences did not work as predicted (see page 712, right column 3rd paragraph). Son *et al* teach that the *P. miliaceum* AlaAT-2 polypeptide only has about 44% sequence similarity to the rat and human homologues (page 712, left column, 2nd paragraph). Son *et al* state that the *P. miliaceum* AlaAT-2 encoding cDNA taught appeared to be the first such cDNA cloned and characterized. Muench *et al* (1994 Plant Molecular Biology 24:417-427) teach the cDNA used by Applicant, encoding a barley AlaAT-2 polypeptide; Applicant acknowledges this fact at page 45 of the instant specification. Muench *et al* teach that the barley AlaAT-2 is 90% identical at the amino acid level to the *P. miliaceum* AlaAT-2 polypeptide (page 422, left column). But, Muench *et al* also teach that barley also appears to have at least three polypeptides having AlaAT activity, and that the gene for the AlaAT-2 polypeptide is not closely related to the genes coding for AlaAT-1 or 3 (page 425, right column 2nd paragraph). Muench *et al* also teach that aminotransferases in plants are know to exhibit broad substrate specificities and that the barley AlaAT-1 and AlaAT-3 may in fact be different aminotransferases possessing minor AlaAT activities (page 425, right column, bottom of the 2nd paragraph). Applicant's example using an alanine dehydrogenase operably linked to the btg-26 promoter produced what Applicant refers to as "non viable" transgenic plants due to

metabolic interference (page 65 of the specification). Applicant's example using a transgene encoding aspartate aminotransferase operably linked to the btg-26 promoter produced the asserted results (pages 65-66 of the specification). Applicant's results using the nitrate reductase promoter operably lined to an AlaAT transgene did not produce the asserted results, Applicant teaches that the nitrate reductase promoter is root specific an not root epidermis specific (pages 66-67 of the specification). Hence, given the limited guidance by Applicant, the nature of the invention, the state of the prior art, the relative skill of those in the art at the time of Applicant's invention and the breadth of the claims, it would have required undue trial and error experimentation to make and use transgenic plants transformed with construct comprising root epidermis specific promoters operably linked to transgene encoding nitrogen utilizing proteins as broadly claimed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-14, 16-26 and 28-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Coruzzi *et al* (U.S. Patent 5,955,651, published 21 September 1999, filed 7 June 1995 and claims priority as a divisional of application No. 08/319,176 filed 6 October 1994) in view of Muench *et al* (1994), Hirel *et al* (1992, Plant Molecular Biology 20: 207-218), Edwards *et al* (1990, Proceedings of the National Academy of Science, USA 87: 3459-3463) and Suzuki *et al* (January 1993, Plant Molecular Biology 21: 109-119).

Coruzzi *et al* teach transgenic plants comprising constructs encoding enzymes involved in amino acid synthesis (column 10, lines 46-57). Coruzzi *et al* teach a method of producing a genetically transformed plant with enhanced nitrogen assimilation/metabolism by transforming said plant with constructs encoding enzymes involved in amino acid synthesis. Coruzzi *et al* teach that the construct can encode an enzyme involved in the assimilation of ammonia into amino acids or in the utilization of these same amino acids in biosynthetic reactions (column 10, lines 48-51). Coruzzi *et al* teaches that it was know in the art at the time of Applicant's invention that overexpression of alfalfa glutamine synthetase in a transgenic plant results in an

increase in total soluble protein content and increased growth (column 5, left column, 1st paragraph). Coruzzi teaches that the steady flow of nitrogen from ammonia to asparagine in this [nitrogen assimilatory] pathway depends upon the recycling of glutamate and α-ketoglutarate (column 2, 2nd paragraph). The fact that alanine aminotransferase recycles glutamate and α-ketoglutarate would have been common knowledge to those of ordinary skill in this art.

Coruzzi *et al* do not teach a transgenic plant transformed with a nucleic acid encoding an alanine aminotransferase (AlaAT) polypeptide or specifically using a root-epidermis-specific promoter.

Muench *et al* teach a nucleic acid encoding a barley AlaAT-2 polypeptide.

Hirel *et al* teach expressing a transgene encoding a soybean root glutamine synthetase gene in a transgenic plant. Hirel *et al* teach that constitutive expression of glutamine synthetase in roots may allow retrieval of residual ammonia from the rhizosphere and would be particularly important in crops such as rice (page 216, right column).

Edwards *et al* teach that the *Phaseolus vulgaris* glutamine synthetase promoter can be used to direct expression of a transgene in nodules, a root structure, in leguminous plants because the promoter is active in vascular and cortical cells of the nodule (page 3463, left column, 1st paragraph).

Suzuki *et al* teach a root-epidermis-specific promoter from the SbPRP1 soybean gene that can be used to produce high expression of a transgene in root epidermis cells (see for example page 116, right column, 3rd paragraph). Suzuki *et al* also teach that

other root-specific promoters were know in the art (page 117, left column, 2nd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to transform a plant with a nucleic acid encoding an alanine aminotransferase as taught by Muench *et al* by modifying the teachings of Coruzzi *et al*. Coruzzi *et al* motivates one of ordinary skill in the art to transform plants with nucleic acids encoding enzymes involved in the utilization of amino acids in biosynthetic reactions; alanine aminotransferase utilizes the product of glutamine synthetase that is explicitly taught by Coruzzi *et al*. It would have been obvious to modify the teachings of Coruzzi *et al* to use a root-epidermis-specific promoter as taught by Suzuki *et al*, said promoter would have been considered a functional equivalent of the promoters recited in the instant claims 14, 26 and 31. Edwards *et al* teaches that those of ordinary skill in the art would have been motivated to direct expression of transgenes involved in nitrogen assimilation in plant root tissues. Coruzzi *et al* teach expressing a glutamate synthetase or an aspartate aminotransferase transgene in a transformed plant. Given the success of Coruzzi *et al* in expressing amino acid synthetase enzyme encoding nucleic acids in transgenic plants and producing transgenic plants with enhanced nitrogen assimilation, one of ordinary skill in the art would have had a reasonable expectation of success in modifying their teachings using the nucleic acid taught by Muench *et al* or the promoter of Suzuki *et al*.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 9 of U.S. Patent No. 6,084,153. Although the conflicting claims are not identical, they are not patentably distinct from each other because the btg-26 promoter taught in the '153 Patent operably linked to the nitrogen assimilation/metabolism enzyme and method of using renders obvious the invention of the instant claims.

Conclusion

17. Claims 15, 27 and 31 are free of the prior art which does not disclose or render obvious the btg-26 promoter.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

David H. Kruse, Ph.D.
21 August 2006

20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.